510(k) Summary
as required by 807.92

K013052

1. Company Identification

JAN 1 5 2002

Konica Corporation
591-7, Kamihirose, Sayama-shi, Saitama-ken 350-1321 Japan
Tel : 011-81-42-954-4529
Fax : 011-81-42-954-6677

2. Official Correspondent

Koji Kubo (Mr.)
Technical Support Department
MG Imaging Equipment & Systems Development Center
Medical & Graphic Company

3. Date of Submission

August. 20, 2001

4. Device Trade name

Konica Laser Imager, DRYPRO model 751/752

5. Common Name

Laser Imager

6. Classification

Laser imager was reviewed by the Radiology Panel and are classified in Class II per 21 CFR 892.2040.

6. Description of Device

Konica Laser Imager DRYPRO model 751/752 are laser imagers convert data from diagnostic equipment such as CT, MRI, DSA, and other medical devices into various intensities, scan and then print the data onto laser imaging film.

This device consists of film supplying unit, film transferring unit, exposing unit, power supplying unit, heat-developing unit, operating unit, power supplying unit and control unit.

This device is certified as a Class I laser product under 21CFR Chapter I, Subchapter J.

This device has no patient contacting materials and is used by trained personnel only. The output of the device is evaluated by additional trained personnel allowing sufficient review to afford identification and intervention in case of malfunction.

7. Intended Use

Konica Laser Imager DRYPRO model 751/752 convert data from diagnostic equipment such as CT, MRI, DSA, and other medical devices into various intensities, scan and then print the data onto laser imaging film.

8. Substantial Equivalence to Predicate Device

Konica Laser Imager DRYPRO model 751/752 are substantially equivalent to our Konica Laser Imager DRYPRO model 722, 510(k) number: K992586. Comparison of the principal characteristics of the two devices, which are pertinent to clinical performance is shown below.

9. Compliance with several standards

Konica Laser Imager DRYPRO model 751/752 comply with the following standards.

Safety:	IEC60601-1-1
Electromagnetic compatibility:	IEC60601-1-2
Applied standard:	FCC, DHHS
Certification granted:	UL, C-UL, C-TICK

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 5 2002

Konica Corporation
% Mr. Shinichi Yamanaka
Cosmos Corporation
319 Akeno, Obata-cho
Watarai-gun, Mie-ken
519-05 Japan

Re: K013052
Trade/Device Name: Konica Laser Imager
Drypro Model 751/752
Regulation Number: 21 CFR 892.2040
Regulation Name: Medical image hardcopy device
Regulatory Class: II
Product Code: 90 LMC
Dated: November 26, 2001
Received: December 3, 2001

Dear Mr. Yamanaka:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (If known): ~~Not known~~ K013052

Device Name: Konica Laser Imager DRYPRO model 751/752

Indications for Use:

The Konica Laser Imager DRYPRO model 751/752 is a laser imager converts data from diagnostic equipment such as CT, MRI, DSA, and other medical devices into various intensities, scan and then print the data onto laser imaging film.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The-Counter Use

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K013052